STATE PROCUREMENT OFFICE

NOTICE OF REQUEST FOR EXEMPTION FROM HRS CHAPTER 103D

'14 MAR 13 P1:59

STATE PROCUREMENT OFFICE
STATE OF HAWAII

TO: Chief Procurement Officer

FROM: HEALTH/SLD
Name of Requesting Department

Pursuant to HRS § 103D-102(b)(4) and HAR chapter 3-120, the Department requests a procurement exemption for the following:

1. Describe the goods, services or construction:
HIV EIA Test Kits & Western Blot Test Kits

2. Vendor/Contractor/Service Provider: Bio-Rad Laboratories

3. Amount of Request: $ 75,000

4. Term of Contract From: ~~3/11/2014~~ 3/13/2014 CK 4/2 To: ~~3/10/2015~~ 3/17/2015 CK 4/20 5. Prior SPO-007, Procurement Exemption (PE): 13-070K

6. Explain in detail, why it is not practicable or not advantageous for the department to procure by competitive means:

State Laboratories' equipment, instrumentation, and software is proprietary to Bio-Rad Laboratories. No other products are USFDA approved to be used with this equipment. The tests to be purchased are USFDA approved for screening of human serum, plasma, and cadaveric serum for antibodies to Human Immundeficiency Virus (HIV) Types 1 (Groups M and O) and/or 2 (HIV-1/HIV-2). These agents have been identified as the causative agents of Acquired Immunodeficiency Virus Syndrome (AIDS). This product, from Bio-Rad Labortories, who acquired Sanofi Diagnostics Pastuer, is marketed by their Genetic Systems Division, uses recombinant and synthetic peptide antigens. The use of this type of antigen is believed to yield accurate results, without a large number of false positives. This product was validated for use by our laboratory in 2007 to screen oral fluid specimens as well as serum, plasma, and cadaveric serum for HIV-1/2 antibodies. It is not practicable or not advantageous for the department to procure by competitive means since our laboratory has already validated the 3rd generation Genetic Systems HIV-1/2 + O EIA test kit and is used to detect HIV antibodies and as contingency to the 4th generation ARCHITECT HIV Ag/Ab Combo Assay(see attached Page 3).

7. Explain in detail, the process that will be or was utilized in selecting the vendor/contractor/service provider:

Our laboratory uses two products for screening of patient specimens for the presence of HIV-1 and HIV-2 antibodies so there is already a fair and open competition. The State Laboratories Division uses the 4th generation ARCHITECT HIV Ag/Ab Combo Assay for HIV-1 /HIV-2 manufactured by Abbott Laboratories to do the initial screening on serum/plasma specimens for the detection of HIV p24 antigen and antibodies to HIV-1 (M and O) and HIV-2 and was initially validated under S.S. No. 11-059-B. The SLD equipment and instrumentation is proprietary to Abbott Laboratories. No other products are USFDA approved to be used with this equipment. Our laboratory currently uses the 3rd generation Genetic Systems HIV-1/2 + O EIA test kits for screening serum and plasma specimens for the presence of HIV-1/2 antibodies. Our laboratory had validated the use of the 3rd generation Genetic Systems HIV-1/2 + O EIA test kit with oral fluid specimens. Our laboratory uses the 3rd generation Genetic Systems HIV-1/2 + O EIA test kit as contingency in the event the Abbott product is not available although we do not have the capability to detect HIV-1 antigen. Similarly, Bio-Rad's equipment and software is proprietary to Bio-Rad and is not USFDA approved to be used with any other products. Both manufacturer's HIV products are currently being used in our laboratory.

8. Identify the primary responsible staff person(s) conducting and managing this procurement. (Appropriate delegated procurement authority and completion of mandatory training required).
*Point of contact (Place asterisk after name of person to contact for additional information).

Name	Division/Agency	Phone Number	e-mail address
Gail Kunimoto	Health/SLD	453-6700	gail.kunimoto@doh.hawaii.gov

All requirements/approvals and internal controls for this expenditure is the responsibility of the department. I certify that the information provided above is, to the best of my knowledge, true and correct.

Linda Rosen MD MPH
Department Head Signature

3-12-2014
Date

For Chief Procurement Officer Use Only

Date Notice Posted: 3/17/14

Inquiries about this request shall be directed to the contact named in No. 8. Submit written objection to this notice to issue an exempt contract within seven calendar days or as otherwise allowed from date notice posted to:

state.procurement.office@hawaii.gov

Chief Procurement Officer (CPO) Comments:

Approval is based on the department's representation that Bio-Rad Laboratories will be used as a contingency plan should Maxim products become unavailable and is the only other manufacturer that produces USFDA Western Blot Test Kits. Approval is granted for the period 3/13/14 to 3/12/15. HRS section 103D-310(c), and HAR section 3-122-112 shall apply (i.e. required to be compliant on the Hawaii Compliance Express) and award is required to be posted on the Award Reporting system.

If there are any questions, please contact Kevin Takaesu at 586-0568, or kevin.s.takaesu@hawaii.gov.

☒ Approved ☐ Disapproved ☐ No Action Required

Chief Procurement Officer Signature

6/24/14
Date

6. Explain in detail, why it is not practicable or not advantageous for the department to procure by competitive means: (continued)

by Abbott Laboratories uses chemiluminescent microparticle immunoassay (CMIA) technology (P.E. 14-017B).

In addition, there are currently only two USFDA approved supplementary or confirmatory tests by western blot for use on HIV-1 serum screen reactive specimens. The USFDA approved western blot test kits are the Cambridge Biotech HIV-1 Western Blot Test Kit manufactured and distributed by Maxim Biomedical, Inc. and the Bio-Rad HIV-1 Western Blot Test Kit. Procurement by competitive means for the Bio-Rad HIV-1 Western Blot Test Kit is not practicable or advantageous for the department to procure by competitive means because our laboratory already performs the Cambridge Biotech HIV-1 Western Blot Test as the primary supplementary/confirmatory test kit for HIV-1 antibody screen reactive specimens (P. E. 13-095K).

We are requesting to have the Bio-Rad HIV-1 Western Blot Test available for contingency use, as may be needed if the test of its only competitor, Cambridge Biotech HIV-1 Western Blot, becomes unavailable or has quality assurance issues.